

**§ 71.18 Petition for exemption from certification.**

A manufacturer, packer, or distributor of a color additive or color additive mixture may petition for an exemption from certification pursuant to part 10 of this chapter. Any such petition shall show why such certification is not necessary for the protection of public health.

**Subpart B—Administrative Action on Petitions****§ 71.20 Publication of regulation.**

The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 721(d)(1) of the act):

(a) A regulation listing in part 73 or 74 of this chapter the color additive on the appropriate list or lists as provided under section 721(b)(1).

(1) Such a regulation may list the color additive for use generally in or on foods, drugs, or cosmetics or for use in coloring the human body, as the case may be, or may prescribe the conditions under which the color additive may be safely used (including, but not limited to, specifications as to the particular food, drug, or cosmetic or classes of food, drugs, or cosmetics in or on which such color additive may be used, or for the material intended for coloring the human body; the maximum quantity of any straight color or diluent that may be used or permitted to remain in or on such food, drug, or cosmetic or article intended for coloring the human body; the manner in which such color additive may be added to or used in or on such food, drug, or cosmetic or for coloring the human body; and any directions or other labeling or packing requirements for such color additives deemed necessary to assure the safety of such use).

(2) Such regulations shall list the color additive only for the use or uses for which it has been found suitable and for which it may safely be employed. Alternatively, the Commissioner shall by order deny the petition, and notify the petitioner of such order and the reasons therefor.

(b) Whenever the Commissioner finds that batch certification is not necessary for the protection of the public health he will, by order, exempt the color additive from the certification procedure. In determining whether certification of a color additive is necessary, the Commissioner will consider the composition of the additive, its manufacturing process, possible impurities, its toxic potential, control and analytical procedures necessary to assure compliance with the listing specifications, and the variability of its composition.

**§ 71.22 Deception as a basis for refusing to issue regulations; deceptive use of a color additive for which a regulation has issued.**

The Commissioner shall refuse to issue a regulation listing a color additive, if in his judgment the data before him show that such proposed use would promote deception of the consumer or would result in misbranding or adulteration within the meaning of the act. Such a finding shall be by order published in the FEDERAL REGISTER subject to the filing of objections and a request for a hearing by adversely affected parties. The issuance of a regulation for a color additive authorizing its use generally in or on a food, drug, or cosmetic shall not be construed as authorization to use the color additive in a manner that may promote deception or conceal damage or inferiority. The use of a color additive to promote deception or conceal damage or inferiority shall be considered as the use of a color additive for which no regulation has issued pursuant to section 721(b) of the act, even though the regulation is effective for other uses.

**§ 71.25 Condition for certification.**

(a) When the Commissioner cannot conclude from the information before him that there is a basis for exempting a color additive from the requirement of batch certification, he will so order by appropriate listing in part 74 of this chapter. The Commissioner's order shall state in detail the specifications that shall be met by the color additive.

(b) Each order shall state a period of time after which use of a color additive subject to batch certification but not

from a batch certified by procedure prescribed in this section would result in adulteration of the product in which it is used.

**§ 71.26 Revocation of exemption from certification.**

If information becomes available to the Commissioner that a color additive that has been granted exemption from certification should not, for the protection of the public health, be so exempted, such exemption will be canceled by a notice published in the FEDERAL REGISTER.

**§ 71.27 Listing and exemption from certification on the Commissioner's initiative.**

Where a petition for a regulation to list a color additive has not been received and the Commissioner has available facts which demonstrate that a color additive should be listed and/or that certification procedure is not necessary in order to protect the public health, he may list such color additive by appropriate regulation and listing in part 73 or 74 of this chapter.

**§ 71.30 Procedure for filing objections to regulations.**

(a) Objections and hearings relating to color additive regulations under section 721 (b) and (c) of the act shall be governed by parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

(b) The fees specified in § 70.19 of this chapter shall be applicable.

**§ 71.37 Exemption of color additives for investigational use.**

(a) A shipment or other delivery of a color additive or of a food, drug, or cosmetic containing such a color additive for investigational use by experts qualified to determine safety shall be exempt from the requirements of section 402(c), 501(a), or 601(e) of the act, provided that the color additive or the food, drug, or cosmetic containing the color additive bears a label which states prominently, "Caution—Contains new color additive—For investigational use only." No animals used in such investigations, or their products, such as milk or eggs, shall be used for food purposes, unless the sponsor or the investigator has submitted

to the Commissioner data demonstrating that such use will be consistent with the public health, and the Commissioner, proceeding as he would in a matter involving section 409(i) of the act, has notified the sponsor or investigator that the proposed disposition for food is authorized. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(b) The person who introduced such shipment or who delivers the color additive or a food, drug, or cosmetic containing such an additive into interstate commerce shall maintain adequate records showing the name and post-office address of the expert to whom the color additive is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department, at reasonable times, he shall make such records available for inspection and copying.

**PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION**

**Subpart A—Foods**

**Sec.**

- 73.1 Diluents in color additive mixtures for food use exempt from certification.
- 73.30 Annatto extract.
- 73.35 Astaxanthin.
- 73.40 Dehydrated beets (beet powder).
- 73.50 Ultramarine blue.
- 73.75 Canthaxanthin.
- 73.85 Caramel.
- 73.90  $\beta$ -Apo-8'-carotenal.
- 73.95  $\beta$ -Carotene.
- 73.100 Cochineal extract; carmine.
- 73.140 Toasted partially defatted cooked cottonseed flour.
- 73.160 Ferrous gluconate.
- 73.165 Ferrous lactate.
- 73.169 Grape color extract.
- 73.170 Grape skin extract (enocianina).
- 73.200 Synthetic iron oxide.
- 73.250 Fruit juice.
- 73.260 Vegetable juice.
- 73.275 Dried algae meal.
- 73.295 Tagetes (Aztec marigold) meal and extract.
- 73.300 Carrot oil.
- 73.315 Corn endosperm oil.